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Via Electronic Submission

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals (CMS-1601-P)

Dear Administrator Tavenner,

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments to the proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2014 (the "Proposed Rule"). MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

Introduction and Summary of Recommendations

We appreciate this opportunity to comment on the OPPS Proposed Rule published in the Federal Register on July 19, 2013.[1] MDMA supports the Centers for Medicare & Medicaid Services' (CMS) attempts to improve the accuracy of payments under the OPPS, and we believe that the

[1] 78 Fed Reg. 43534 (July 19, 2013).

Proposed Rule attempts to continue the agency's progress toward this goal. However, we do have several serious concerns with the proposed regulation that may in fact lead to inaccurate payment rates that would inhibit beneficiary access to medical technologies.

MDMA's comments and recommendations focus on the following issues:

- Use of data from the new "Implantable Devices Charged to Patients" cost center
  - **MDMA supports the continued use of data from the new "Implantable Devices Charged to Patients" cost center to create a distinct cost-to-charge ratio (CCR) for use in calculating relative weights for procedures using these devices, and we recommend that CMS use this information in the final rule.**

- Expanded payment bundles and composite ambulatory payment classifications (APCs)
  - **CMS should not implement the comprehensive APCs and expanded packaging proposals for at least one year to allow stakeholders sufficient time to study the methodology used by CMS and to further assess the appropriateness of the proposed APCs and payment rates.**
  - **In general, to ensure that APC configurations and payments remain adequate to protect access to innovative devices and services, CMS should require complete and correct coding for packaged services.**
  - **We ask that CMS make annual reports to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel) on services subject to CMS's expanded packaging policies.**
  - **CMS should further study the effects of the expanded packaging, report on any changes in utilization or access to care, and consult with relevant stakeholders well in advance of proposing any additional packaging proposals.**

- Payment for new technologies
  - **CMS should implement the device pass-through provisions as Congress intended by approving additional applications for technologies that meet the criteria for pass-through payments.**
  - **CMS should ensure that products and services that have applied for and are appropriate for pass-through payment status or New Technology APCs receive appropriate APC assignments, especially in light of the expansion of packaging and composite APCs.**

- Payment for specific codes and APCs
  - **CMS should create a new APC entitled, Level IV Upper GI Procedures or Upper GI Transoral Procedures with a payment amount of at least $5,000 for CY 2014 and assign Healthcare Common Procedure Coding System (HCPCS) code C9724 to this newly created APC.**
  - **CMS should assign 0334T to a New Technology APC with a payment rate for $14,000 - $15,000 or establish a new pass-through category for the implants used to perform this procedure.**
  - **CMS should assign HCPCS code C9736 to APC 0174 to ensure sufficient reimbursement for RF ablation of uterine fibroid(s))**

Use of Data from the New "Implantable Devices Charged to Patients" Cost Center

MDMA has been concerned for many years about the effects of "charge compression" on Medicare's payment rates. Charge compression is the tendency of CMS's rate setting methodology to underestimate the costs of advanced, higher cost devices. Although more advanced, higher cost devices tend to be subjected to lower markups than less expensive supplies, CMS historically has used a single CCR to estimate the costs of these supplies and devices. In the FY 2009 inpatient prospective payment system (IPPS) final rule, CMS moved forward to address the issue of charge compression by splitting the current cost center for "Medical Supplies Charged to Patients" into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." This was consistent with

Research Triangle Institute, International's ("RTI") report on charge compression, which found that "the largest impact on the MS-DRG relative weights could result from correcting charge compression for devices and implants."[2]

In CY 2013 OPPS final rule, CMS explained that it now has a sufficient amount of data from this cost center to generate a meaningful analysis.[3] CMS proposes to continue to use these data in the CY 2014 OPPS Proposed Rule to create a distinct CCR for use in calculating relative weights for procedures using these devices.[4] MDMA supports this proposal because it helps to address longstanding concerns about charge compression and provide more appropriate reimbursement for procedures involving use of implantable devices, and we recommend that CMS use this information in the final rule.

Expanded Packaging and Composite APCs

The Proposed Rule for CY 2014 would make significant changes to payment for procedures using medical devices. First, CMS proposes to create 29 new comprehensive APCs to pay for device-dependent services associated with 136 HCPCS codes.[5] The comprehensive APC will include not only all of the items and services that are packaged under the current OPPS rule, but also nearly all adjunctive items and services, such as:

- all services proposed to be packaged, conditionally or unconditionally, elsewhere in the Proposed Rule;
- all adjunctive services provided during the delivery of the comprehensive service;
- room, board, and nursing costs necessary to deliver the outpatient service, regardless of whether or not the stay extends beyond a single day;
- all hospital-administered drugs pursuant to a physician order, excluding pass-through drugs.

CMS also proposes to expand packaging to include seven new categories of items and services:

[2] RTI, A Study of Charge Compression in Calculating DRG Relative Weights, Jan. 2007, at 11; see also RTI, Refining Cost to Charge Ratios for Calculating APC and MS-DRG Relative Payment Weights, July 2008, at 9.
[3] 77 Fed. Reg. at 68210, 68224 (Nov. 15, 2012).
[4] 78 Fed. Reg. at 43548.
[5] Id. at 43556.

1. Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;
2. Drugs and biologicals that function as supplies or devices when used in a surgical procedure;
3. Certain clinical diagnostic laboratory tests;
4. Procedures described by add-on codes;
5. Ancillary services, such as chest x-ray, that are assigned status indicator "X;"
6. Diagnostic tests on the bypass list; and
7. Device removal procedures.[6]

CMS explains that these proposals are intended to improve the accuracy of payment rates under the OPPS and provide hospitals with incentives to provide care efficiently. We support these goals, but we also believe that more analysis of the proposals is needed to understand if they can achieve these goals. MDMA has not been able to determine if the proposed rates are appropriate because CMS's initial data files included several errors and the revised data files became available shortly before the deadline for submitting these comments. Analysis of the initial data files CMS released found significant, interrelated errors and inconsistencies in calculation of the proposed payment rates throughout the OPPS. The complex analysis required to model the proposed expansions in packaging and changes in APC assignments using the corrected files CMS released on August 28, 2013 could not be completed before the end of the comment period. Thus, we do not believe that we and other interested members of the public had the opportunity to comment meaningfully on these proposals, and we do not believe they should be implemented in 2014.

MDMA has commented previously about its concerns about expanded packaging under the OPPS. While we share CMS's desire to provide incentives to furnish care efficiently, we also understand that expanded packaging can have the opposite effect. In particular, because Medicare payment to hospital outpatient departments is based on procedures provided in a single day, the hospital has an incentive to provide the lowest cost item or service included in an APC. If that service does not fully address the patient's needs, the hospital could receive better reimbursement by bringing the patient back for a second visit or admitting the patient for

[6] Id. at 43540.

inpatient care than by providing a more costly option within the same APC. Moreover, when an APC's payment rate is significantly less than the cost of a technology, hospitals have a strong disincentive to use that technology, even if it could reduce the costs of care at a later date. CMS's use of expanded packaging has the risk of encouraging hospitals to forego performing needed services and using new technologies that may be more resource intensive during one visit but could save the patient future outpatient department visits or inpatient care.

CMS's current proposals could have wide-ranging effects on access to care in hospital outpatient departments. The proposals affect the calculation of the payment rates not only for the 29 new comprehensive APCs and the hundreds of items and services in the seven categories proposed to be packaged, but also for any service furnished in conjunction with those APCs. According to CMS, the comprehensive APC proposal is "effectively budget neutral" because the new APCs are entirely derived from existing services reported on Medicare claims. CMS estimates that expanding packaging to seven new categories of items and services would redistribute approximately four percent of the estimated CY 2013 base year expenditures under the OPPS, although the effect on individual services would vary.

A preliminary review of the proposed rates reveals significant and unpredictable changes in reimbursement for services using advanced medical devices. Changes in payment rates for the comprehensive APCs range from -5 percent to 189 percent. These dramatic changes could have an effect on access to care, especially if they result in payment rates for each expanded bundle of services that are lower than what hospitals are currently paid for those services. Although most of the comprehensive APCs would have increased payment rates compared to CY 2013, it is not apparent that the increases accurately reflect the costs of the packaged services due to the breadth of the packaging proposals and the variety of items and services provided with each separately payable service. CMS notes that comprehensive APC costs exceed the device-dependent procedure costs by an average of 11 percent, or less than $1000 per claim. A thorough analysis of the data for each service is needed to verify that CMS's data and methodology are appropriate.[7] Unfortunately, we have not been able to conduct that analysis in the limited time between release of CMS's data and this comment period. We support the recommendation of the HOP Panel to delay implementation of comprehensive APCs and expanded packaging until the

[7] Id. at 43561.

Panel can review data on these proposals at its Spring 2014 meeting. In order to ensure that stakeholders are able to provide meaningful comments, we urge CMS to make the data and its methodology available to stakeholders well in advance of the Spring HOP Panel meeting. In the meantime, CMS should not implement the comprehensive APCs and expanded packaging proposals for at least one year.

Complete and Accurate Coding for Packaged Items and Services

Regardless of whether CMS expands packaging within the OPPS, the agency's ability to calculate appropriate payment rates depends on the accuracy and completeness of the claims data. To ensure that the agency has the data it needs, we have urged the agency in the past to require complete and correct coding for packaged services. We have seen that hospitals are much more likely to report all of codes and costs for packaged services when there is a requirement to do so. In the Proposed Rule, CMS recognizes this fact, explaining that because device-dependent APCs were created, employing device-to-procedure and procedure-to-device edits, CMS has seen a "significant improvement and stabilization in reporting of costs." [8]

CMS now concludes that "hospitals are fully accustomed to appropriate cost reporting under the OPPS such that special billing constraints are unnecessary,"[9] and CMS proposes to remove the edits. We do not share CMS's confidence that hospitals will continue to report codes for packaged services if they are no longer required to do so. **To this end, CMS should require complete and correct coding for packaged services and continue to employ device-to-procedure and procedure-to-device edits.** All items and services that are not individually reimbursed must be included on the claim to provide CMS with essential data for future OPPS updates. We believe that continued reporting by CMS on utilization of all packaged services is essential to ensure that the Medicare's payment policies do not restrict beneficiaries' access to necessary care. **We ask that CMS make annual reports to the HOP Panel on services subject to CMS's expanded packaging policies. CMS also should continue to consult with relevant stakeholders well in advance of proposing any additional packaging proposals.**

[8] Id. at 43695.
[9] Id.

Payment for New Technologies

MDMA is concerned that increased packaging could artificially prevent new technologies from qualifying for pass-through payments and assignment to New Technology APCs. Both pass-through payments and New Technology APCs ensure that new technologies and procedures can be accessed by Medicare beneficiaries in a timely manner and that hospitals can integrate these technologies with assurance that there will be adequate payment. These vehicles are important, and the bar to satisfy the criteria for these assignments is high. Equally important is the role these New Technology APC and pass-through assignments provide in allowing CMS to collect payment data to ensure that the eventual clinical APC assignment best reflects the resources and the costs of those procedures and technologies and that the eventual clinical APC placement is clinically coherent.

As CMS implements expanded packaging and bundling, it must protect the integrity of the pass-through and New Technology APC provisions by continuing to apply them to innovative new technologies. Specifically, CMS must continue to grant New Technology APC or pass-through status to appropriate devices for at least two years before transitioning to clinical APCs. As we described above, CMS's expanded use of packaging is likely to limit the data pool available for future OPPS updates. Since CMS has implemented these policies, it is even more important to ensure that CMS uses the full time allotted to a new technology under these provisions to collect accurate data on its costs.

MDMA requests CMS to ensure that products and services that have applied for and are appropriate for pass-through payment status or New Technology APCs receive appropriate APC assignments, especially in light of the expansion of packaging and composite APCs. Only when data are collected can a rational decision about if, how, and when to package be made.

Appropriate APC Placement for HCPCS Code C9724

Gastroesophageal Reflux Disease (GERD) is reflux and regurgitation of the contents of the stomach into the esophagus. However, the esophagus is not designed to handle the acidic fluids

in the stomach. The reflux of these fluids is not only painful and uncomfortable, but can burn the esophagus, cause chronic inflammation, and lead to major damage and potentially cancer of the esophagus. Over 60 percent of the elderly have frequent GERD, and over 14 million Americans have GERD so frequently and severely that they experience symptoms every single day. Approximately 30-40 percent of GERD patients require surgical intervention. This intervention is a surgical procedure is called a "fundoplication."

In the last six years, physicians have performed more than 12,000 transoral fundoplication procedures. But, patient access to transoral fundoplication has been stymied due to hospital outpatient payment amounts under Medicare that cover only 25 percent of the hospital's costs when a transoral fundoplication procedure is performed on a Medicare patient in their facility.

In the Proposed Rule, CMS reported geometric mean costs of $7,504.96 for HCPCS code C9724, Endoscopic full-thickness plication of the stomach using endoscopic plication system, includes endoscopy, and assigned it to APC 0422 – Level III Upper GI Procedures with a proposed CY 2014 payment rate of $1,967.36.

Transoral fundoplication is not the only upper GI procedure on the horizon that will have a hospital outpatient cost profile that is substantially more than the payment level proposed for APC 0422 – Level III Upper GI Procedures. There are other procedures, such as those for bariatric surgery, that are being developed with a transoral approach and will also need a new APC.

Therefore, MDMA urges CMS to take the following action in the CY 2014 Final HOPPS Rule:

- **Create a new APC entitled, Level IV Upper GI Procedures or Upper GI Transoral Procedures with a payment amount of at least $5,000 for CY 2014 and assign HCPCS Code C9724 to this newly created APC.**

Appropriate Placement of APC 0334T

CMS proposes to assign CPT code 0334T to APC 0208 which has a proposed payment rate of $4171.56 for CY 2014.[10] MDMA disagrees with this proposed assignment.

CPT Code 0334T, Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized) when performed, includes image guidance when performed (eg., CT or fluoroscopic), became effective July 1, 2013 and is currently assigned to APC 0208 with a payment rate of $3,759.

The procedure described by 0334T is a new procedure that has been reported under CPT Code 27280, *Arthrodesis, sacroiliac joint (including obtaining graft)* which is on and is proposed to continue to be on, the inpatient only list. The basis for creating 0334T was to distinguish between open sacroiliac (SI) joint fusions and minimally invasive SI joint fusions. The minimally invasive SI joint fusions described by 0334T may safely and effectively be performed in the outpatient hospital setting; open SI joint fusions cannot be performed on an outpatient basis. Minimally invasive SI joint fusion saves an inpatient hospitalization, results in much less blood loss than open procedures, allows patients to be walking and getting physical therapy the day after surgery and has been shown in the peer reviewed literature to relieve pain 90 percent of the time. Over 8,500 minimally invasive fusions have been performed in the United States - virtually all of them on an inpatient basis.

Minimally invasive SI joint fusion requires the use of newly developed advanced implant technology. These implants are entirely different from screws and other fasteners used in traditional, open orthopedic procedures. One example of such implants is the iFuse implant. This is a triangular, titanium coated porous implant designed to interact biologically with the bone to promote fusion. It is FDA cleared for sacroiliac joint fusion. The screws used in open procedures are intended to fixate bone using threads and loosen over time due to rotation. The triangular iFuse implants are three times stronger than screws, have a larger surface area to support the heavily loaded SI joint and do not rotate because of their triangular

[10] Id. at 43590.

shape. The porous titanium coating is biologically interactive, so unlike a screw, it promotes fusion. These sorts of implants have never been used before and their costs are not accounted for in the outpatient prospective system and are not included in the payment for APC 0208. In order for beneficiary to have access to minimally invasive SI joint fusion in the outpatient setting, CMS needs to establish a payment that is appropriate to cover the cost of these implants as well as the procedure. **MDMA recommends that CMS should assign 0334 to a New Technology APC with a payment rate for $14,000 - $15,000 or establish a new pass-through category for the implants used to perform this procedure.**

Appropriate APC Placement for HCPCS Code C9736

CMS should assign HCPCS code C9736 to APC 0174 to ensure a sufficient reimbursement amount for RF ablation of uterine fibroid(s)). This new Level II HCPCS code which became effective July 1, 2013, has been assigned to APC 131[11]. Considering the cost of the equipment $40,640.00, the one-time use handpiece $2,854.00, dispersive pads $80.00, other std supplies, plus the costs involved for the outpatient setting, the proposed payment amount of $3,487.15 for APC 131 is insufficient. As CMS attempts to categorize like procedures with clinical and cost similarities, it should be noted that in APC 131 there are no costly handpieces required for any of the procedures. A more appropriate category for C9736 would seem to be APC 0174 – which contains RF ablation procedures for renal and liver – similar in clinical nature, procedure time, and cost.

Conclusion

In conclusion, MDMA is encouraged by CMS's willingness to address important issues in the OPPS and to improve payment accuracy, and we look forward to working with CMS in the future to continue to make improvements. Thank you.

Sincerely,

Thomas C. Novelli

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[11] Id. at 43588